



## Study of Socio Demographic Predictors of Adherence of Anti Retroviral Therapy (ART) among HIV Positive Patients - A Case Control Study

Bhautik P Modi<sup>1</sup>, Vaibhav Gharat<sup>2</sup>, Prakash Patel<sup>3</sup>, Sunil Nayak<sup>4</sup>, Rachna Prasad<sup>5</sup>, R K Bansal<sup>6</sup>

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### Author's Affiliation:

<sup>1</sup>Asst Prof, Dept of Community Med, GMERS, Gandhinagar; <sup>2</sup>Asst Prof, Dept of Community Med, GMERS, Valsad; <sup>3</sup>Asst Prof, Dept of Community Med, SMIMER, Surat; <sup>4</sup>Professor & Head, Dept. of Community Med, GMERS, Valsad; <sup>5</sup>Asso Professor; <sup>6</sup>Professor & Head, Dept. of Community Med, SMIMER, Surat

### Correspondence

Dr. Vaibhav Gharat  
drvvgmd@gmail.com

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## ABSTRACT

**Introduction:** After starting free Anti Retroviral Therapy (ART) in India, challenge has changed from gaining access to taking the treatment correctly and consistently in order to realize the rewards of improved health status, and reduced morbidity and mortality from HIV. This study was aimed to identify of socio-demographic risk factors responsible for non-adherence to ART.

**Methodology:** This Case Control Study was conducted at ART centre where all patients with poor adherence percentage i.e.  $\leq 95\%$  of Treatment Adherence were denoted as 'Case' and good adherence percentage i.e.  $> 95\%$  of Treatment Adherence were denoted as 'Control'. The 'Pill Count method' was used to measure the adherence level.

**Results:** Mean age of 104 cases and 208 unmatched controls was 36.29 years and 39.21 years respectively ( $p < 0.05$ ). Females were more common among cases than controls. Total 15.4% of cases and 7.7% of controls were from the rural area (OR: 2.18 (1.04 - 4.56) and  $p$ -Value  $< 0.05$ ). Post-test counselling was not done in 10% of cases and 4% of controls. [OR: 2.66 (1.02 - 6.96) &  $p$ -Value  $< 0.05$ ].

**Conclusion:** Poor adherence was more in younger, female, rural residence, low family income, disclosure of HIV positive status and patients undergone post test counselling.

**Keywords:** Anti-Retroviral Therapy (ART), Adherence, Pill count, Disclosure, Counselling

## INTRODUCTION

The first case of HIV/AIDS in India was identified in Chennai in 1986.<sup>1</sup> And 25 years later, based on HIV Sentinel Surveillance 2008-09, it is estimated that 23.9 lakhs people are infected with HIV in India of whom 39% are female and 4.4% are children.<sup>2</sup> The Government of India had launched the free ART programme on 1 April 2004, starting with eight tertiary-level government hospitals in the six high-prevalence states. As per annual report of NACO for the year 2011-2012, around 4.86 lakhs PLHAs including 28,225 children are receiving free

ART through 342 ART Centres and 685 Link ART Centres.<sup>2</sup>

Thus, the challenge has changed from gaining access to taking the treatment correctly and consistently in order to realize the rewards of improved health status, and reduced morbidity and mortality from HIV. To achieve these health goals, adherence to ART has emerged as both the major determinant and the Achilles' heel of this success. World Health Organization (WHO) recommendations on the use of ART in resource-limited settings recognize the critical role of adherence in order to achieve clinical

cal and programmatic success. Antiretroviral adherence is emerged as second strongest predictor of progression to AIDS and death, after CD4 count.

Patient variables include socio-demographic factors (age, gender, race/ethnicity, income, education, literacy, housing status, insurance status, HIV risk factors) and psychosocial factors (mental health, substance use, social climate and support, knowledge and attitudes about HIV and its treatment).<sup>3,4,5</sup>

This study was aimed to identify of socio-demographic risk factors responsible for non-adherence to ART and help to regulate the treatment through better counselling and ultimately preventing the development of resistance to ART.

## METHODOLOGY

This was a Case Control Study where all of the eligible cases and controls, selected without matching, conducted at ART centre of Surat Municipal Institute of Medical Education & Research (SMIMER), a tertiary care hospital of Surat, Gujarat, India. Around 2080 HIV positive patients are taking Anti-retroviral Therapy (ART) from ART centre of SMIMER at the time of study. For calculating sample size of the study, Odds Ratio (OR) of 2.117 and 95% confidence interval (CI) of 1.2 - 3.8 calculated for presence or absence of care giver to patients was taken from the study done at ART Center at Government Medical College, Thrissur in South India.<sup>6</sup>

The prevalence of presence of care giver was assumed to be 20% among the adherent (Control) group. Using the Open-Epi Software, and a ratio of non-adherent cases to adherent controls of 1:2, a type I error of 5%, sample size of 104 non-adherent patients (Cases) & 208 adherent patients (Controls) was calculated to give 80% power to estimate an Odds Ratio of 2.117 for a given exposure.

The 'Pill Count method' was used to measure the adherence level of the patient for the course of the treatment of the last month. PLHAs aged more than 18 years; diagnosed as HIV positive and taking ART at least since last one year at the time of interview and willing to give informed written consent were included in the study. All of these patients were analyzed for adherence level during their current visit by above mentioned method and categorized in to 'case' and 'control'.

All patients with poor adherence percentage i.e.  $\leq 95\%$  of Treatment Adherence were denoted as 'Case'. All patients with good adherence percentage i.e.  $> 95\%$  of Treatment Adherence were denoted as 'Control'.

For interviewing total 312 PLHAs (104 cases and 208 controls), a total of 365 PLHAs had to be approached, as 53 PLHAs could not be included in the study for a variety of reasons. The reasons for non-inclusion included detection of HIV positive less than one year for twenty four PLHAs, refusal to participate in the study by seventeen PLHAs. Twelve PLHAs were willing to give information, but they were not willing to give written consent, so they were excluded from the study. Owing to ethical consideration, permission was obtained from the Institutional Ethical Committee of the Surat Municipal Institute of Medical Education and Research, Surat before commencing of the study. Permission from the National AIDS Control Organization and Gujarat State AIDS Control Society were also obtained for conducting this study.

The tools used for collection of data comprised of a pre-designed and pre-tested semi structured questionnaire developed with the help of all the stakeholders. This questionnaire was filled up by oral interview technique. The information thus collected was entered on a Microsoft Excel spreadsheet and analyzed with the help of Statistical Package for Social Science (SPSS) software and presented in the forms of tables, charts and diagram.

## RESULTS

This unmatched Case Control study was done among the patients attending ART centre of Surat Municipal Institute of Medical Education and Research. In this study, total 104 cases and 208 controls were recruited and information was collected using semi-structured questionnaire.

**Table 1: Age wise Distribution of Patients**

Age group (Years)	Case (%)	Control (%)	Total (%)
<20	1 (1.0)	0 (0.0)	1 (0.3)
21-25	6 (5.8)	4 (1.9)	10 (3.2)
26-30	16 (15.4)	29 (13.9)	45 (14.4)
31-35	31 (29.8)	36 (17.3)	67 (21.5)
36-40	26 (25.0)	66 (31.7)	92 (29.5)
41-45	16 (15.4)	35 (16.8)	51 (16.3)
46-50	5 (4.8)	23 (11.1)	28 (9.0)
>50	3 (2.9)	15 (7.2)	18 (5.8)
<b>Total</b>	<b>104 (100.0)</b>	<b>208 (100.0)</b>	<b>312 (100.0)</b>
<b>Mean<math>\pm</math>SD</b>	<b>36.29<math>\pm</math>7.59</b>	<b>39.21<math>\pm</math>7.72</b>	<b>38.24<math>\pm</math>7.78</b>

**p-Value 0.001**

Table 1 reveals age-wise distribution of cases and controls. Out of total 312 study participants, 104 were cases and 208 were controls. Mean age of total 312 patients was 38.24 year with standard deviation of 7.78 years. Among cases, the majority of respondents (29.8%) belong to age group of 31 to 35 year. Among controls, the maximum number of

respondent (31.7%) from age group of 36 to 40 years of age. As demonstrated in the table 1, mean age of cases was 36.29 years and mean age of controls was 39.21 years. This difference was statisti-

cally significant (p-Value < 0.05). This indicates younger people are more likely to have poor adherence.

**Table 2: Relation of Socio-demographic Profile with Patients**

Variable	Case (n=104) (%)	Control (n=208) (%)	Odds Ratio (CI)	p-Value
<b>Gender</b>				
Female	46 (44.2)	64 (30.8)	<b>1.78 (1.1 - 2.90)</b>	<b>0.019</b>
Male	58 (55.8)	144 (69.2)		
<b>Residence</b>				
Rural	16 (15.4)	16 (7.7)	<b>2.18 (1.04 - 4.56)</b>	<b>0.035</b>
Urban	88 (84.6)	192 (92.3)		
<b>Religion</b>				
Muslim	4 (3.8)	5 (2.4)	1.62 (0.42 - 6.18)	0.473
Hindu	100 (96.2)	203 (97.6)		
<b>Type of Family</b>				
Nuclear	76 (73.1)	141 (67.8)	1.29 (0.76 - 2.17)	0.339
Joint	28 (26.9)	67 (32.2)		
<b>Disclosure of HIV status</b>				
Not disclosed	3 (2.9)	2 (1.0)	3.06(0.50 - 18.60)	0.202
Disclosed	101 (97.1)	206 (99.0)		
<b>Presence of Care Giver</b>				
No	27 (26.0)	32 (15.4)	<b>1.93(1.8 - 3.44)</b>	<b>0.024</b>
Yes	77 (74.0)	176 (84.6)		

**Table 3: Pre and Post Test Counselling of Patients**

Counselling	Case (n=104) (%)	Control (n=208) (%)	Odds Ratio (CI)	p-Value
Pre-test counselling Not-done	71 (68.3)	83 (39.9)	3.24 (1.97- 5.32)	<0.001
Pre-test counselling Done	33 (31.7)	125 (60.1)		
Post-test counselling Not-done	10 (9.6)	8 (3.8)	2.66 (1.02 - 6.96)	0.039
Post-test counselling Done	94 (90.4)	200 (96.2)		

Gender wise distribution of respondent shows females were more common among cases than controls. Odds ratio 1.78 indicates females are 1.78 times more likely to having poor adherence than males. Table 2 reveals 15.4% of cases and 7.7% of controls were from the rural area. This difference was statistically significant [OR: 2.18 (1.04 - 4.56) and p-Value < 0.05]. This indicates people living in the rural area were more likely to miss the dose of ART. There was no effect of religion [OR: 1.62 (0.42 - 6.18) & p-Value > 0.05] and type of family [OR: 1.29 (0.76 - 2.17) & p-Value > 0.05] on the adherence of ART treatment. Table 2 reveals that almost all patients had disclosed their HIV status to any of the relative or friend. Only 2.9% of cases and 1% of controls had not disclosed to anyone among spouse, friends and relatives. 26% of cases and 15.4% of controls had not any of care givers present at their home to take care of them. This difference was statistically significant [OR: 1.93(1.08 - 3.44) & p-Value <0.05]. This indicates patients not having any of care givers at home were more likely to miss the dose of ART.

Mean family income of case was Rs.5572.11 per month and of control was Rs.7752.40. This differ-

ence was statistically significant (p-Value < 0.001). This indicates patients with low family income were more likely to miss doses.

Patients distributed according Modified Prasad's Socio-economic Classification. According to table 7, the maximum number (34.6%) of case were from socio-economic class of III and the maximum number of controls (38.9%) were from socio-economic class of II. 7.7% of cases and 10.6% of controls were from socio-economic class I.

Post-test counselling was not done in 10% of cases and 4% of controls. This difference was also statistically significant [OR: 2.66 (1.02 - 6.96) & p-Value < 0.05]. This indicates patients that had not undergone post-test counselling were 2.66 times more likely to have poor adherence than patients who had undergone a post-test counselling.

**DISCUSSION**

The current case control study was conducted to evaluate association of socio-demographic factors and patient factors with adherence to ART. For that, 104 patients with adherence rate of ≤ 95%

during last month of treatment were selected and for comparison 208 patients with adherence rate of >95% were selected randomly without matching.

Table 1 reveals that there was statistically significant difference in the mean age of the case and control (p-Value - 0.001). The mean age of cases was 36.29 years while mean age of control was 39.21 years. This indicates younger people were more likely to have poor adherence. These findings reveal the fact that the majority of the PLHAs were in the most productive phase of their life and their loss could even imply the economic collapse of families. This implies the urgency of the need to mount remedial measures. This finding agrees with the finding of Abah et al (2004) that age of respondent influences adherence to ART. Other studies also indicate that younger age is associated with poor adherence.<sup>3,4,7</sup> According to NACO women account for 39.3% of the total prevalence of HIV in India.<sup>8</sup> In our study also representativeness of females was nearly 34.3% of the total number of patients. In similar study conducted in Gujarat females contributed to 34% of the respondents, which is consistent with our study finding.<sup>9</sup>

Table 2 reveals that females were 1.78 times more likely to having poor adherence than males. This is in consistent with the finding of Wastiet al.<sup>10</sup> Thus, younger age and female gender was associated with poor adherence. This group of patients are more vulnerable to emotional stress and they need more emotional support in comparison of patients from other group. Lack of sufficient social support to this age group might be the reason for their poor adherence.

Table 2 reveals that people living in the rural area were more likely to miss the dose of ART. Low level of literacy, poor understanding of HIV and poor understanding of benefits of ART of patients living in rural area can be the reason for their poor adherence. Stigma and discrimination is also more prevalent in the rural area as compare to urban area. Thus, fear of disclosure of HIV status due to daily dose of medicine results in poor adherence of ART among patients living in rural area.

There was no effect of type of family on the adherence of ART treatment. Type of family has its own advantage and disadvantage. Advantage of joint family is patient can get support from the family member but stigma and discrimination can act as disadvantage of joint family. In nuclear family these things are opposite.

Large number of migrants comes to Surat city from different states of India. Most of them are single male migrants. Lack of social restriction and social support among these migrants leads to high prevalence of high risk behaviour which ultimately leads

to high prevalence of HIV/AIDS among this population. Social support is utmost importance for the good adherence to ART. According to number of studies, common predictors of nonadherence include stressful life events, lack of social support, and the inability to correctly identify the drug regimen or describe the relationship between adherence and drug resistance.<sup>4,5,11,12</sup> Number of studies suggests that lower income is associated with nonadherence.<sup>3,4,13,14</sup>

Fear of disclosure of HIV status is associated with low level of adherence. The threat of social stigma may prevent people living with HIV from disclosing their HIV status. This may serve as a barrier to ART adherence. Table 2 reveals that patients not having any of care givers at home were more likely to miss the dose of ART. This result is in consistent with the study done at ART Center at Government Medical College, Thrissur in South India.<sup>6</sup> In a study done by Rintamaki et al (2006) in Chicago, the effect of social concern on treatment adherence were evaluated. People with high stigma concerns were 3.3 times more likely to be non-adherent to their medication regimen than those with low concerns.<sup>15</sup>

Table 3 shows that, patients that had not undergone post-test counselling were 2.66 times more likely to have poor adherence than patients who had undergone a post-test counselling. Counselling must start from the first contact visit by the clinical team and should include preparing the patient for treatment and providing psychosocial support through an identified guardian/treatment buddy and through support networks. All patients should undergo at least two counselling sessions before the initiation of ART. The period of investigations should be utilized for counselling and treatment preparation. All efforts should be made to trace patients who have defaulted or are lost to follow-up.

## CONCLUSION

There are many variables found to be associated with poor adherence to ART. The socio-demographic variables associated with poor adherence were younger age, female gender, rural residence and low family income, disclosure of HIV positive status and patients undergone post test counselling. Ensuring good adherence to the treatment is imperative for the success of the national programme as well as for the prevention of drug resistance.

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